

REMARKS

I. Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-24 are pending in this application.

The Office Action indicates that claims 1-24 were rejected under 35 U.S.C. § 112, first paragraph, "because the specification, while being enabling for fibromyalgia, does not reasonably provide enablement for all of the disorders cited in the claims", and fails to enable the "use of the invention commensurate in scope with these claims". The Office Action further states that "while the specification enables for the treatment of fibromyalgia, there is no teaching about the treatment of these various disorders. " No further basis of rejection is provided in the Office Action.

This rejection is respectfully traversed.

With respect to an enablement rejection under 35 U.S.C. § 112, it is well-settled law that the examiner bears "the initial burden of setting forth a reasonable explanation as to why [he/she] believes that the scope of protection provided by [the] claim is not adequately enabled by the description of the invention provided in the specification." *In re Wright*, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). To object to a specification on the grounds that the disclosure is not enabling with respect to the scope of a claim sought to be patented, the examiner must provide evidence or technical reasoning substantiating those doubts. See *Id.*; and MPEP § 2164.04, emphasis added.

The claims are directed to methods of treating specified disorders by administering a specified compound. Commensurate with the scope of the claims, the specification describes treating the claimed disorders with the specified compounds. Methods of administration are also described, for example, on page 116, last paragraph of the specification; which states, *inter alia*, "[d]etermination of the proper dosage for a particular situation is within the skill of the art". As to the disclosure of how to prepare the compounds and compositions stated in the claimed methods of treatment, the specification is replete with such disclosure; and the Office Action does not indicate that the specification is not enabled for lack of such disclosure. Accordingly, Applicants submit that the specification, coupled with the knowledge of the

ordinarily skilled artisan, fully enables the ordinarily skilled artisan to make and use the claimed invention. In contrast, the Office Action appears to reject the scope of the claims, but does not provide the requisite basis for such a rejection.

The Office Action acknowledges that the claims are enabled for treating fibromyalgia, possibly due to inclusion of working examples in the specification related to fibromyalgia. However, the Applicants further note that the lack of working examples is one consideration in the overall analysis of lack of enablement. See *In re Colianni*, 561 F.2d at 224, 195 U.S.P.Q. at 153. As stated in the MPEP, § 2164.02, "[t]he specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation."

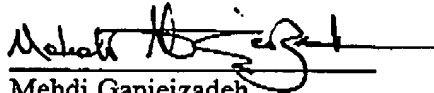
In light of all of the above, Applicants respectfully submit that the Office Action has not met the burden of establishing a *prima facie* case for lack of enablement under U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request this rejection of the pending claims.

Applicants submit that this application is now in condition for allowance, which allowance is respectfully solicited.

If the Examiner believes that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at 734-622-3831.

Respectfully submitted,

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